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3. Remarks

Claims 46-49, 51-52, and 64-67 are currently pending in the application. Claims 1-45, 50, and 53-63 have been previously canceled without prejudice. In this response, claims 48, 52, and 65-67 are cancelled without prejudice. Applicants reserve the right to pursue the subject matter of the cancelled claims in future applications.

Claim 46 has been amended to introduce the limitations of claims 48, 52 and 65 into the claim. Claim 46 has also been amended to specify that the patient is a cancer patient. Support for this amendment may be found, for example, at page 70, lines 11-34. Claim 49 has been amended to provide proper antecedent basis for the term "chemotherapeutic agent." No new matter has been added.

35 U.S.C. § 103(a)

All pending claims remain rejected under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. published application 2004/0028687 to Waelti, and Yndestad et al. (*Cardiovasc. Res.* 2002 April, 54(1):175-82), in view of U.S. Patent 5,674,704 to Goodwin. Applicants respectfully traverse.

The Supreme Court in *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007) upheld past precedent that requires a *prima facie* case of obviousness to provide evidence as to why one of skill in the art would combine the elements of the claim in the fashion claimed. Applicants respectfully note that the Examiner's case for obviousness has not met this burden of proof.

The TSM test captures a helpful insight: A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art. Although common sense directs caution as to a patent application claiming as established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007).

Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the market place; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at

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issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”). *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007).

As is clear from cases such as *Adams*, a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known. *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007).

Thus, a conclusion of *prima facie* obviousness must be supported by evidence, a showing by some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references to arrive at the claimed invention. It is well established that “[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.” *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

An examiner may often find every element of a claimed invention in the prior art, but this does not take into account any inventive contribution. Rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach is impermissible under the current law. Applicants suggest this is precisely what has occurred.

The claimed invention must be viewed as a whole. The claimed invention is to a method of reducing anthracycline-induced cardiotoxicity by inhibiting the 4-1BB pathway. There is no teaching, suggestion or motivation in Yndestad, Goodwin or Waelti (or generally known in the art in 2003) to combine the prior art references to make the claimed invention. There is

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absolutely no information in Yndestad, Goodwin or Waelti suggesting a nexus between the 4-1BB pathway and chemotherapy-induced cardiotoxicity. This is the inventive contribution of Applicants. One of skill in the art in August of 2003 (our earliest priority date) would not connect this disparate art without the benefit of having read the present application.

Applicants respectfully submit that the only suggestion for the Examiner's combination of the isolated teachings of the applied references improperly stems from Applicants' disclosure. It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. "Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention." *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546, 48 USPQ2d 1321, 1329 (Fed. Cir. 1998). As the KSR Court stated "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."

Applicants respectfully request the rejection under 35 U.S.C. §103(a) be properly withdrawn. Applicants maintain that the claims as set forth are in form for allowance. Applicants' attorney encourages the Examiner to call him at the number below if it would be helpful in advancing the prosecution of this application.

Respectfully submitted,



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